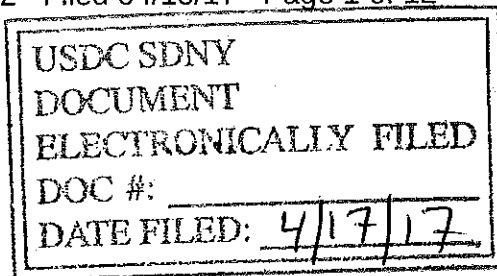


UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



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IN RE: ELIQUIS (APIXABAN) PRODUCTS
LIABILITY LITIGATION

This document relates to: ALL ACTIONS

Civil Action No. 1:17-md-2754-DLC

⁹
~~PROPOSED~~ CASE MANAGEMENT
ORDER NO. 3: ORDER
ESTABLISHING PROTOCOL FOR
ELECTRONICALLY STORED
INFORMATION ("ESI")

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A. SCOPE

1. **General.** The procedures and protocols set forth in this Order shall govern the production of ESI in this matter, unless the Parties agree in writing to change them or they are changed by the Court at the request of a Party. To the extent that non-parties produce documents in this case, the Parties agree to request that such non-parties adopt this Order.

2. **Scope of Production.** This Order does not address the scope of Defendants' production. The Parties shall meet and confer regarding custodial and non-custodial sources of potentially discoverable documents, including the production of databases or other structured data.

3. **Subsequent Orders.** This Order shall not preclude subsequent agreements between the Parties relating to ESI, nor shall it preclude any Party from seeking relief from or an amendment to this Order upon a showing of good cause.

B. DEFINITIONS

4. "Electronically stored information" or "ESI," as used herein, means and refers to computer-generated information or data, stored in or on any storage media located on computers,

file servers, disks, tape, USB flash (“thumb”) drives or other real or virtualized devices or media, as such information is defined in Federal Rule of Civil Procedure 34(a)(1)(A).

5. “Native Format” means and refers to the format of ESI in which it was generated or as it is used by the Producing Party in the usual course of its business and in its regularly conducted activities.

6. “Media” means an object or device, including but not limited to a disc, tape, computer, drive, or other device, whether or not in the Producing Party’s physical possession, on which data is or was stored.

7. “Metadata” means and refers to: (i) information embedded in a Native File that is not ordinarily viewable or printable from the application that generated, edited, or modified such Native File; and (ii) information generated automatically by the operation of a computer or other information technology system when a Native File is created, modified, transmitted, deleted, or otherwise manipulated by a user of such system.

8. “OCR” means and refers to an optical character recognition file which is created by software used in conjunction with a scanner that is capable of reading text-based documents and making such documents searchable using appropriate software.

9. “Party” or “Parties” means and refers to the named Plaintiffs and/or Defendants in the above-captioned matter. “Producing Party” refers to a Party (or non-party that avails itself of this Order) that produces documents in this litigation.

C. PRODUCTION

10. **Production Format.** Unless otherwise specified herein, a Producing Party shall produce electronic documents in black-and-white, single page, 300 DPI, Group IV* tagged image file format (“TIFF”) images with corresponding extracted full text and, to the extent

possible, affiliated metadata containing the fields identified in the attached Exhibit A. A Producing Party: (1) shall produce PowerPoint files in color (with the exception of any PowerPoint files Defendants Pfizer Inc. (“Pfizer”) and Bristol-Myers Squibb Company (“BMS”) already have processed as part of their regulatory files); and (2) shall accommodate reasonable requests for production of specific images in color, including of other file types and/or of PowerPoint files in Pfizer’s and BMS’s regulatory files. A Producing Party may de-duplicate exact duplicates based on MD5-Hash value prior to production in a manner that does not break up document families (such as emails and attachments), but the original ESI shall be preserved. With regard to custodial files, a Producing Party may de-duplicate globally or only within a custodian’s file, but the metadata shall indicate each custodian in whose files the document was found. If a Producing Party intends to de-duplicate within non-custodial files, or between custodial files and non-custodial files, the metadata provided with the produced documents shall indicate from which other source(s) the documents were de-duplicated. All productions will include these additional specifications:

- a. A load file for images;
- b. A delimited load file (.dat) containing a field with the full path and filename to Native Files produced and the metadata fields identified in Exhibit A (for ESI) (unless the filename is privileged);
- c. Document level .txt files for all native documents containing extracted full text; provided, however, that OCR text can be provided if extracted text is not available (in which case the parties shall meet and confer regarding the reason extracted text is not available) or if the document has been redacted pursuant to this protocol or the Protective Order in place in this litigation;

- d. Bates number branding and appropriate Confidentiality designations (if any) on the face of the image; and
- e. Slipsheets may be used as placeholders for any email attachments that are not responsive, which should indicate “non-responsive attachment not produced” or language to that effect.

11. Production of Native Format ESI.

- a. A Producing Party shall produce Excel spreadsheets, audio files, and video files in their Native Format. For Excel spreadsheets with redactions:

(1) Pfizer shall produce them as TIFF images, but shall ensure that the images are legible, and the Parties shall meet and confer with regard to any issues with how spreadsheets with redactions are compiled (*e.g.*, cell numbers and headers); and (2) BMS shall produce them as Native Excel files.
- b. If production in Native Format is necessary to decipher the meaning, context, or content of a document produced in TIFF, the Producing Party will honor reasonable requests for either the production of the original document for inspection and copying or production of the document in Native Format, including (but not limited to) documents Pfizer or BMS already have processed from their Investigational New Drug Application(s) (“INDs”) and New Drug Applications (“NDAs”).
- c. All metadata contained in or associated with each file will be produced to the extent technologically possible. The Native Format document shall be renamed with a Bates number. For each document whose Native Format

is a multimedia (video) file, a TIFF placeholder shall be produced in addition to the Native File.

12. **Production of SAS Files.** The parties shall meet and confer regarding whether (and, if so, in what format) Defendants shall produce Statistical Analysis System (“SAS”) files for clinical trial data.

13. **Load File.** To the extent production is made in an electronic format susceptible to creation of a Load File (and, where an electronic format is not susceptible to the creation of a Load File, the parties shall meet and confer regarding the reason a Load File is not available), the Producing Party shall provide a Load File to accompany the TIFF images that are produced to facilitate the use of the produced images by a document management or litigation support system as described above. Load Files shall indicate document breaks, page breaks within a single document (but if, and only if, the Producing Party creates or uses page breaks when it processes its documents), and contain the parent/child (Email/Attachment) relationships of documents, when possible.

14. **Appearance and Content.** Other than as required in this paragraph, no electronic document may be intentionally manipulated to change how the source document would have appeared, without prior agreement of the Receiving Party, except that hidden information (such as redline or comments) will be revealed. Additionally, all emails will be produced with the BCC field visible, to the extent it is available with the document. “Dynamic fields” (such as auto-date and time) shall be produced showing the field code (*e.g.*, [AUTODATE]), rather than the values for such fields existing at the time the file is processed. Therefore, subject to any appropriate redaction and any revealed hidden information, each document’s electronic image shall convey the same information and image as the original

document. This means that font size, bold, italics, underline and other font features shall be maintained. If a document is illegible or unviewable to the Receiving Party, the Parties shall discuss appropriate measures to address the issue through an agreed-upon resolution, such as, for example, enlarging font size.

15. **Document Numbering for TIFF Images.** Each page of a document produced as TIFF images shall have a legible, unique Bates number electronically “burned” onto the image at a location that does not obliterate, conceal or interfere with any information from the source document. The Bates number for each document shall be created so as to identify the Producing Party. Each Producing Party shall have a unique identifying name. The Bates number shall not include underscores or other non-alphanumeric characters. Each page of each production shall have a unique number of up to eight digits. The unused digits of the unique number shall be filled with placeholder zeros (0) to facilitate electronic sorting of the documents. Any Producing Party producing ESI in Native Format, as set forth above, shall produce a slip sheet in Black and White Group IV* TIFF that is endorsed with the Bates number.

16. **Production Media.** The Producing Party shall produce documents on readily accessible computer or electronic media as the Parties may hereafter agree upon, including CD-ROM, DVD, external hard drive (with standard PC compatible interface or access to a secure Online Repository agreed upon by the Parties) or via secure FTP site. Each piece of Production Media shall be assigned a production number or other unique identifying label corresponding to the date of the production of documents on the Production Media, as well as the sequence of the material in that production. The Producing Party shall accompany all document productions with a transmittal cover letter identifying the documents produced and an Excel spreadsheet

production log containing the Bates ranges for each distinct custodian or source (*e.g.*, share drive).

17. **Redactions.** To the extent that a document is produced in redacted form, any redactions shall be clearly indicated on the face of the document, and the metadata for that document should indicate that there is a redaction, and the reason(s) for any redaction(s). Where a responsive document contains both redacted and non-redacted content, the Producing Party shall produce the remainder of the non-redacted portions of the document. The production of a document in a redacted form does not affect the Producing Party's obligation, if any, to properly document and substantiate the assertion of privilege over the content on a privilege log. Except as provided above in paragraph 11(a), documents that are to be produced in Native Format, but that require redactions, may be produced as TIFF images (with extracted text) with the relevant portions redacted, or if a TIFF image production is not technically feasible, the Producing Party may produce a copy of the Native File with the relevant portions replaced with "[REDACTED]" or a similar mark. If modification of a Native File is required for redaction purposes, metadata information associated with that file should remain unchanged unless it also requires redaction.

18. **Confidentiality of Produced ESI.** Nothing in this Order is intended to be inconsistent with the Stipulated Protective Order that the Court will enter in this MDL (Case Management Order No. 2), and where anything in this Order is inconsistent with the terms of the Stipulated Protective Order, the terms of the Stipulated Protective Order shall prevail. If a document is produced subject to a claim that it is protected from disclosure under the Protective Order, the word "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" shall be burned electronically on each page of such document.

D. MISCELLANEOUS

19. **English Language.** To the extent any data exists in more than one language, the data shall be produced in English, if available. If no English version of a document is available, the Producing Party does not have an obligation to produce an English translation of a document.

20. **Cooperation.** The Parties shall, as necessary, meet and confer to exchange information regarding issues associated with any production of ESI, including, but not limited to, database field definitions and structure or document delivery mechanisms.

21. **Variance.** Any practice or procedure set forth herein may be varied by written agreement of the Parties.

22. **Paper Discovery.** Nothing in this Order is intended to interfere with, preclude, alter, or otherwise affect the Parties' independent obligations to engage in discovery involving and, where appropriate, produce materials that exist only in paper format. All paper documents shall be produced as static images. The images will be black-and-white, single page, 300 DPI, Group IV* TIFF images with corresponding OCR text in document level .TXT format and standard load files, which can be used with commercially available litigation software packages. Producing paper documents in such form does not change their character from paper documents into ESI. All other metadata that does not exist as part of the original document need not be produced for paper documents produced as TIFF images. The parties shall meet and confer with respect to the unitizing of hard copy documents and grouping of documents into families.

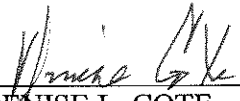
23. **Replacement Images.** In the event that an already produced document or set of documents has to be re-produced or a new load file or "overlay" is produced for any production, the new production shall always maintain the same Bates number for any re-produced

documents, with the addition of a suffix at the end of the Bates number, and without creating a new database record.

24. **Metadata as Evidence.** This Order shall not be construed to affect whether information contained in the metadata produced shall be admissible evidence about the corresponding document; rather, the Parties' positions with regard to admissibility shall be preserved for trial.

SO ORDERED:

New York, New York
April 17, 2017



DENISE L. COTE
United States District Judge

EXHIBIT A – FIELDS AND METADATA TO BE PRODUCED

Field	Sample Data	Scanned Docs	Email and E- Docs	Comment
PRODBEG [Key Value]	ABC00000001	Yes	Yes	Beginning production number
PRODEND	ABC00000008	Yes	Yes	Ending production number
PRODBEGATT	ABC00000009	Yes	Yes	Beginning production number of parent document in a family
PRODENDATT	ABC00001005	Yes	Yes	Ending production number of last page of the last attachment in a family
NUMATTACH	2		Yes	Number of attachments
FILESIZE			Yes	Size of application file/document (in KB)
CUSTODIAN	LAST, FIRST Smith, John	Yes	Yes	Custodian in whose file the document is produced (the value always will be a single name; <i>i.e.</i> , only one custodian will be listed)
ALL CUSTODIANS	LAST, FIRST Smith, John Doe, Jane	Yes	Yes	Custodian(s) that possessed the document—multiple custodians separated by semicolon (BMS will populate this field as appropriate; Pfizer's metadata will be empty / blank for all documents)
SOURCE	XYZ SHAREDRIIVE	Yes	Yes	For non-custodial files (BMS will populate this field as appropriate; Pfizer's metadata will be empty / blank for all documents)
OTHER SOURCE	XYZ SHAREFILES	Yes	Yes	Additional locations for documents found in a custodial file and a non-custodial area or found in multiple non-custodial areas (BMS will populate this field as appropriate; Pfizer's metadata will be empty / blank for all documents)

Field	Sample Data	Scanned Docs	Email and E- Docs	Comment
NATIVEFILE	NativesW \00000001.xls	N/A	Yes	Path and file name for Native File on production media
FILEDESC	Microsoft Office 2007 Document	N/A	Yes	Description of the type file for the produced record
FOLDER	\My Documents\ Document1.doc	N/A	Yes	Original source folder for the record produced
FILENAME	Document1.doc	N/A	Yes	Name of original electronic file as collected
DOCEXT	DOC	N/A	Yes	File extension for email or e-doc
PAGES	2	Yes	Yes	Number of pages in the produced document (not applicable to Native File productions)
AUTHOR	John Smith	N/A	Yes	Author information as derived from the properties of the document
LASTAUTHOR	LAST, FIRST Smith, John		Yes	User last saving the document
DATECREATED	10/09/2005	N/A	Yes	Date that non-email file was created as extracted from file system metadata
DATELASTMOD	10/09/2005	N/A	Yes	Date that non-email file was modified as extracted from file system metadata
SUBJECT	Changes to Access Database	N/A	Yes	"Subject" field extracted from email message or metadata properties of the document
FROM	John Beech	N/A	Yes	"From" field extracted from email message
TO	Janice Birch	N/A	Yes	"To" field extracted from email message
CC	Frank Maple	N/A	Yes	"Cc" or "carbon copy" field extracted from email message
BCC	John Oak wood	N/A	Yes	"Bcc" or "blind carbon copy" field extracted from email message

Field	Sample Data	Scanned Docs	Email and E- Docs	Comment
DATESENT	10/10/2005	N/A	Yes	Sent date and time of email message (mm/dd/yyyy format, time zone set to GMT)
DATERCVD	10/10/2005	N/A	Yes	Received date and time of email message (mm/dd/yyyy format, time zone set to GMT)
CONVERSATION ID			Yes	From Outlook or Lotus Notes
MESSAGEID			Yes	From Outlook or Lotus Notes
MASTERDATE/EMAILDATASORT			Yes	Master sort date (e.g., for email attachments, the sent date)
REDACTED	Yes/No	Yes	Yes	Identifies whether a document is redacted
REDACTION REASON	Privilege; Privacy	Yes	Yes	Identifies the reason for a redaction
CONFIDENTIALITY	HIGHLY CONFIDENTIAL	Yes	Yes	Text of confidentiality designation, if any
TEXTPATH	Text\W.txt	Yes	Yes	Path to *.txt file containing extracted or OCR text
PRODVOL	VOL001	Yes	Yes	Name of the Production Volume
MD5 Hash Value	098f6bcd 4621d 373cade4e 832627b4f6	N/A	Yes	MD5 Hash value of document